APR 0 1 2003

K030153

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Summary of Safety and Effectiveness

Submitter:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Karen Cain Manager, Regulatory Affairs Telephone: (574) 372-4219 Fax: (574) 372-4605
Date:	January 8, 2003
Trade Name:	*ZCA*® All-Poly Acetabular Cup, Snap-In
Common Name:	All Polyethylene Acetabular Cup
Classification Names and References:	Hip joint metal/polymer semi-constrained cemented prosthesis (21 CFR § 888.3350)
Predicate Devices:	*Trapezoidal-28*® "Snap-On" Acetabular Cup (preamendment device), manufactured by Zimmer, Inc. Müller Snap-On Acetabular Cup (postamendment device), manufactured by Zimmer, Inc. Zimmer Non-Metal Backed Acetabular Cup for Cemented Fixation (formerly Astel), K901240, cleared March 26, 1990 ULTIMA All-UHMWPE Cemented Acetabular Cups, manufactured by Johnson & Johnson, K924115, cleared November 24, 1992 *Trilogy*® Acetabular System Elevated Rim Liners, manufactured by Zimmer, K934765, cleared April 29, 1994
Device Description:	The *ZCA* Snap-In Cup is a single unit manufactured from ultra-high molecular weight polyethylene (UHMWPE). The interior of the cup is designed to allow snap fitting of a 32 mm head into the

articular surface through material interference around the inner diameter rim. The *ZCA* Snap-In Cup is designed with a neutral face and is provided in outer diameter sizes ranging from 49 to 61 mm in 2 mm increments to fit varying anatomical requirements. The *ZCA* Snap-In Cup is hemispherical in shape and has four press-fit PMMA cement spacers affixed to the outer diameter to centralize the cup and help maintain a uniform 3 mm cement mantle. Radiopaque stainless steel wires at the dome and equator are used to determine the location and orientation of the component radiographically. Grooves and scallops on the outer surface are used for optimal cement interdigitation.

Intended Use:

The acetabular cup is intended for cemented use in skeletally mature individuals undergoing primary or revision surgery for rehabilitating hips damaged as a result of noninflammatory degenerative joint disease (NIDJD) or its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

Comparison to Predicate Devices:

The acetabular cups listed above are substantially equivalent to each other and the *ZCA* Snap-In Cup in that all are manufactured from the same or similar materials and are intended to replace the bearing surface of the acetabulum.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 01 2003

Ms. Karen Cain
Manager, Regulatory Affairs
Zimmer, Inc.
P.O. Box 708
Warsaw, IN 46581-0708

Re: K030153
Trade Name: ZCA All Poly Acetabular Cup, Snap-In
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JDI
Dated: January 8, 2003
Received: January 16, 2003

Dear Ms. Cain:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K030153

Device Name:

ZCA® All-Poly Acetabular Cup, Snap-In

Indications for Use:

The acetabular cup is intended for cemented use in skeletally mature individuals undergoing primary or revision surgery for rehabilitating hips damaged as a result of noninflammatory degenerative joint disease (NIDJD) or its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K030153

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)